DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

IL 12-2002-003
In Reply Refer To: 124

March 6, 2002

OFFICE OF RESEARCH AND DEVELOPMENT INFORMATION LETTER

SOLICITATION OF APPLICATION FOR THE
RESEARCH ENHANCEMENT AWARD PROGRAM (REAP)
REHABILITATION RESEARCH AND DEVELOPMENT SERVICE

1. Purpose. The Veterans Health Administration (VHA) Rehabilitation Research and Development Service (RR&D) Service announces the opportunity for Department of Veterans Affairs (VA) medical centers to compete for support by the Research Enhancement Award Program (REAP).

2. Background

a. The purpose of the REAP is for RR&D to promote and support groups of VA RR&D investigators that are not affiliated under the domain of a currently funded RR&D Center.

b. The goal of this program is to increase RR&D capacity by assisting VA sites that already show promise, as demonstrated by a history of RR&D peer reviewed research and career development funding.

c. Funds of $250,000 for 5 years would be committed to create a core of investigators to build capacity and facilitate the development of proposals in under funded, but critical areas of rehabilitation. These include but are not limited to aphasia, neurodegenerative diseases (including ALS), upper-extremity prosthetics, multiple sclerosis (rehabilitation), movement disorders, and neuropathic pain.

3. Eligibility. Investigators under this initiative are to conduct related rehab research in area specified. Each investigator's research should be primarily be focused on the nature of the contribution to research in the REAP program. To qualify for application, there must be at least three VA funded principal investigators engaged in research projects at the time of application submission. There must be activity in one of the following categories:

a. VA Merit Review funded (RR&D, MRS or HSR&D) principal investigator at the time of application submission

b. VA RR&D Research Career Scientist receiving VA salary at the Research Career Scientist (RCS) or Senior Research Career Scientist level, or

c. VA RR&D Career Development awardee at the Research Career Development (RCD), Advanced Research Career Development (ARCD), Career Development Enhancement (CDE) or Associate Investigator (AI) level

NOTE: *These investigators are referred to as the "eligible investigators." In addition to eligible investigators, VA investigators with research support other than Merit Review may be included if they contribute to and strengthen the Program. Investigators who do not meet the criteria in subparagraph 3a through 3c are not qualified for consideration as eligible investigators.*

4. Objective. One of the main objectives of REAP is the training of new investigators. The application needs to exhibit the prior success of eligible investigators in training pre and post-doctoral fellows and junior investigators, and outline ongoing and future plans for recruiting and training new investigators.

5. Pilot Projects. As part of REAP, new and innovative research ideas can be explored as pilot projects to acquire data supporting the validity and feasibility of these ideas. Carefully conceived pilot projects are encouraged to explore novel approaches and establish feasibility for larger scale RR&D projects. Investigators should clearly document in their application the added value that REAP funds will provide to current RR&D efforts. The pilot studies are a vehicle to demonstrate collaboration of qualifying investigators supporting investigators, and trainees.

6. Local Support. The VA medical center and the Veterans Integrated Services Network (VISN) must support the RR&D REAP application, and agree to provide a minimum 25 percent protected time for the investigator coordinating program activities.

7. Funding. Support may be requested for recurring costs up to $250,000 per year. Programs with three funded investigators will receive up to $200,000; programs with four or more funded investigators will receive up to $250,000. Funds for recurring costs may be used for:

a. Personnel costs for Ph.D. investigators, programmers, statisticians, economists, research assistants, etc.,

b. Support for pilot projects or current project enhancements

c. Support for graduates, and

d. Supplies, equipment and infrastructure support.

NOTE: *Funds for trainees my be included in the budget, but will not be distributed until a trainee has been identified and approved by RR&D Service.*

8. Start-Up Costs. In addition to recurring costs, a one-time request of up to $100,000 may be submitted for equipment start-up. Requests must be well justified. Shared support by the VA medical center, VISN, or affiliated institution is encouraged and should be documented. Shared support may include cost sharing, facility renovation or equipment costs, service contracts on equipment, or personnel costs.

9. Awards. It is anticipated that up to four RR&D REAP awards will be given with funding beginning July 2002. Programs will be funded up to 5 years. If the number of qualifying projects/awards or investigators falls below three, a plan must be submitted to Central Office describing how this deficiency will be addressed. If this deficiency is not corrected within nine months, funding will be phased out. Renewal will depend on a competitive continuation application, and upon the availability of funds.

10. Program Performance. Each Program will be required to submit to VHA Central Office an annual budget and research performance report. Performance measures will include:

a. Importance of major findings from the Program and active dissemination findings via peer reviewed publications and presentations with significant citations within the literature.

b. Peer-reviewed funding of investigators,

c. Status of the training program

d. Number and quality of pilot projects underway, and

e. Evidence of local, national, and international recognition of the Program and/or its members. ***NOTE****: Unsatisfactory performance will result in probationary status or termination of funding*.

11. Evaluation. RR&D REAP applications will be evaluated on the basis of the following major components.

a. Scientific qualifications of the investigators affiliated with the Program.

b. Plans to develop new and innovative research programs to enhance the current research activities in RR&D.

c. Planned training for new investigators.

d. Appropriateness of the budget and ability to administer the funds.

e. Commitment to the Program by the VA medical centers, VISN, or affiliated institution.

f. Compliance with eligibility criteria.

12. Dates. Deadline for receipt of applications is March 31, 2002. Proposals will be reviewed in April, and results announced by May 2002.

13. Contact. Inquiries may be directed to Laura Bowman at 202-408-3680

S/ James F. Burris, M.D. for
John R. Feussner, M.D., M.P.H.
Chief Research and Development Officer

Attachment

DISTRIBUTION: CO: E-mailed 3/6/2002
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 3/6/2002

ATTACHMENT A

PREPARING MERIT REVIEW PROPOSALS FOR SUBMISSION TO REHABILITATION RRESEACH AND DEV ELOPMENT SERVICE

1. GENERAL

a. **Forms and Instructions.** An investigator who plans to submit a pilot study proposal or full research proposal to Rehabilitation Research and Development (RR&D) for Merit Review needs to contact the Associate Chief of Staff (ACOS) for Research and Development (R&D) at the local Department of Veterans Affairs (VA) medical facility to obtain information concerning forms and instructions. For pilot study proposals, submit the original and twenty-five copies following the same format used for full research proposals.

b. Number of Submissions. No proposal should be submitted to more than one VA R&D Service at a time. Principal Investigators (PIs) with an ongoing research project or program in any of the VA R&D Services who wish to explore an additional research proposal may submit a proposal to RR&D, subject to Letter of Intent (LOI) approval.

c. Human Subjects. If human subjects are to be used in the course of the proposed project, a VA Form 10-1223, Report of the Institutional Review Board (IRB), is required, as well as VA Form 10-1086, VA Research Consent Form.

d. **Experimental Devices and Investigational Drugs.** Clinical studies that include the use of experimental devices or drugs of unproven safety and efficacy are subject to both VA and Food and Drug Administration (FDA) regulations. For clinical investigations involving experimental devices or investigational drugs, an Investigation Exemption application must be submitted to FDA prior to submission of the proposal to RR&D (see VHA Handbook 1200.5).

e. **Withdrawing a Proposal.** If an investigator wishes to withdraw a proposal, RR&D must be notified promptly by telephone, followed by a memorandum addressed to the Director, RR&D Service.

f. Transfers. When a principal investigator with a pending Merit Review proposal transfers to another VA facility, RR&D must be notified in advance of the transfer and must receive the required forms from the new VA facility (including approvals by the facility R&D Committee and appropriate subcommittees). The required forms must be received by RR&D in a timely manner for the proposal to be reviewed.

g. **Routing of Proposals.** Each proposal package is routed through the VA medical facility Office of the ACOS for R&D, the R&D Committee, the medical center Director and any other appropriate channels.

h. **Mailing of Proposals.** Proposals are to be sent by:

(1) Regular Mail to:

Merit Review Proposal Coordinator
Program Analysis and Review Section (122)
Rehabilitation Research and Development Service
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

(2) **Express Mail to:**

Merit Review Proposal Coordinator
Program Analysis and Review Section (122)
Rehabilitation Research and Development Service
Department of Veterans Affairs
1400 "I" Street, NW; Suite 700
Washington, DC 20005

i. **Electronic Submission of Proposals.** In addition to the hard copy requirements previously listed, electronic submission of proposals is required as follows:

(1) **Disk.** The disk size must be 3 ½ in. The disk format may be high or low density (720K or 1.44 meg). It must be MS DOS, Windows, Windows 95-98, or NT formatted.

(2) **Brief Statement of Research Objectives.** The Brief Statement of Research Objectives (Abstract) must be file one on the disk. The file format must be plain text or Microsoft Word.

(3) **Graphics.** Graphic pictures, drawings, etc. are not to be submitted electronically. Only the full text (narrative) of the proposal is required, and it must be file two on the disk. The file format must be plain text or Microsoft Word.

(4) **Labeling.** The disk must be labeled with the date, PI's name, project number, and title. The disk must be included with the hardcopy proposal submission.

2. COMPONENTS OF APPLICATION PACKAGE: Submit the following:

a. A typed single-spaced original proposal, one side only (unstapled). It will be used as the master file copy. (May use black spring clips or rubber bands; do not use silver butterfly clips). Attach a buck slip with the station contact person and phone number.

b. Ten copies of VA Form 10-1313-1, Merit Review application, and VA Form 10-1313-2, Summary Description of Program, duplicated back-to-back.

c. Twenty-five copies of the proposal duplicated back-to-back (stapled). If the proposal is too thick for a staple, then secure with a heavy black clip. Do not use silver butterfly clips. Check for proper page order.

d. Six copies of up to three selected papers that are representative of the applicant's best work (optional). Publications are not be placed in an appendix; they are to be enclosed with, not attached to, the proposal.

e. A memorandum addressed to the Director, RR&D Service (122) with the names of two or more scientists who are qualified to review the proposal will be accepted. Information on reviewers need to include their area of expertise and contact information, (address, phone numbers, email address, etc.). The name of any reviewer that may have a conflict of interest, if asked to review the proposal, may be included.

f. If the proposal is a resubmission of a continuation project, a not-funded project, or a deferred project, it is required that six stapled copies of the previously reviewed proposal and six stapled copies of each reviewers' critique be included. Also include fifteen white copies of the Summary Statement from the previously reviewed proposal.

3. PAGE FORMAT AND PAGE NUMBERING: Submit the proposal on 8.5 x 11 inch paper, leaving a 1 inch margin on all sides. Where necessary, use a blank sheet of paper as a continuation sheet for the forms. Type material single-spaced in a type style that prints capital letters one-eighth (1/8) of an inch tall to ensure a clean imprint suitable for reproduction, scanning and readability. Type the name of the principal investigator in the lower right portion of each page and number each page consecutively starting with the face sheet, e.g., Smith-1 to Smith-22. Prepare an index or table of contents and place after VA Form 10-1313-2.

4. ORDER OF VA FORMS: VA Forms 10-1313-1 through 10-1313-8 should be arranged in numerical order.

5. VA FORM 10-1313-1. Provide ten copies along with VA Form 10-1313-2, back-to-back

a. Item 1. Insert LOI number.

b. Item 2. Leave blank.

c. Item 3. Type in proposal number assigned by RR&D Service in large numbers.

d. Item 4. Type in merit review round (e.g., winter/year or summer/year).

e. Item 5. Complete.

f. Item 6. Provide the complete mailing address for the VA medical center or health care facility.

g. Item 7. Social Security Number. Complete for PI and co-PI, if applicable.

h. Item 8. Provide the **date** the PI last submitted a proposal to Rehab R&D for merit review.

i. Item 9. The last name of the **principal investigator** should be typed first in capital letters, followed by the first name and initial(s). List telephone number(s) of the PI. The PI needs to be the person responsible for the scientific and technical direction and completion of the work proposed (submission by a single principal investigator is preferred; however, co-PIs may be identified).

j. Item 10. The **proposal title** should not exceed 72 typewritten spaces. Be specific and descriptive in choice of title to assist readers to quickly identify the overall program objectives. If the proposal title has been changed since a prior submission or since the LOI was approved, print "NEW TITLE" directly above the typed title.

k. Item 11. The amount requested each year should be the same as the totals listed on other forms within the application. The "total" is total funding requested for all years.

l. Item 12. VA employment status refers to current or projected salary status. Principal Investigators who have less than a 5/8 part-time appointment must have an eligibility exception in order to submit a proposal. A copy of the 5/8 exception request and the Chief R&D Officer approval memo for each PI and co-PI must be included with all copies of merit review proposals (including pilots). A current VA-paid appointment of at least 5/8 time is required before a research project can be funded (see to VHA Handbook 1200.15).

m. Item 13. Mark the appropriate box indicating the PI salary source.

n. Item l4. Check appropriate box for NEW or ONGOING. A proposal is considered "new" when it has never been submitted or reviewed by RR&D Service. A proposal is considered "ongoing" when it has been funded for a period of time (1, 2, or 3 years) by RR&D Service. It may also be ongoing (continuation) even though it acquires a new title or there is a major shift in programmatic objectives. In the blank space next to the ONGOING box include entire proposal number and previous review date, (i.e., A2672R; 1/99). Because each RR&D proposal is considered separately, "Number of Projects in Program" should be one.

o. Item 15, Program Code and Cost Center. Insert the three-digit Program Code (822 for RR&D) and the Cost Center number (8122 for RR&D).

p. Item 16: Insert the primary research program area and primary specialty area. ***NOTE:*** *The primary specialty area is primary board or graduate field of study.*

q. Items 17 and 18. Complete for each PI and Co-PI.

r. Item 19. Complete and ensure that designated items are included in the proposal.

s. Item 20. Beginning with the current year, for VA, complete and identify Service from which research support is received. Provide the same information for non-VA funding.

t. Item 21. Complete for each PI and Co-PI. Insert the date the PI entered on duty at VA or expected date of entry if appointment is pending. If there has been a break in service, list the date of most recent appointment. Prior VA service may be indicated as parenthetical information.

u. Signature Blocks. An original signature for the PI(s) and the ACOS for R&D, or designee, is required, with current date. In signing this VA form, the ACOS certifies that the proposal is complete administratively and all required reviews have been conducted. Print or type beside or below the signature the name and phone number of a person to contact if administrative issues arise.

6. VA FORM 10-1313-2, Summary Description of Program

a. **Identifying Information.** Check the box marked "project" to indicate that you are describing a project. Provide the identifying information requested: PI name; project title (72 characters or spaces maximum); and key words from the National Library of Medicine, permitted Medical Subject Headings (MeSH).

b. **Brief Statement of Research Objectives (Abstract).** The primary purpose of this section is to provide a brief and accurate overview of the proposal. It should include the research, development, evaluation program objectives (immediate and ultimate), the significance of the research to the VA health care system, and the general research design. A clear, concise description of the proposed study should be provided, however, technical details should not be included. List key words that best describe the scientific disciplines encompassed and the research areas addressed by the research.

7. TABLE OF CONTENTS: List all proposal items and sections, including but not limited to, narrative section; specify page numbers for each major proposal component and element of the proposal (include each part of the Appendix). The Table of Contents should be inserted immediately after VA Form 10-1313-2.

8. VA FORM 10-1313-3, Current Funds and First Year Request

a. Check the appropriate box to indicate this form applies to a project and insert the identifying information (PI(s) name and project title).

b. List all personnel involved in the project, including the PI under the block titled "PERSONNEL." Provide their names and identify their degree(s).

(1) Secretaries are not allowed as study personnel.

(2) Intergovernmental Personnel Agreements (IPAs) are discouraged. If such arrangements are absolutely necessary for the successful implementation of the project, strong justification with a detailed explanation of estimated costs is required. Identify the name, role in the program and percent of effort under project personnel. Do not include cost. Also identify these IPA personnel under "ALL OTHER EXPENSES" with the title "IPA." The projected cost is to be under the section "FIRST YEAR REQUESTED FUNDS."

c. Under the block titled "ROLE IN PROGRAM" identify for each person their role (i.e., principal investigator, co-principal investigator, investigator, research technician, programmer analyst) and identify their grade and step.

d. List the percent of total professional or technical effort devoted to the project by all personnel identified.

(1) List costs for all personnel, which should be proportional to the time, devoted to the project. Do not include cost-of-living increases, within grade increases, or anticipated promotions in the personnel category. All personnel projections should be straight-lined for the duration of the project.

(2) List a subtotal for the personnel dollars requested.

e. The first year request column should include all RR&D funds being requested for the projected first 12 months of the project.

f. The current year funding column should include RR&D funds available to the investigator for the 12-month period preceding the first year request if this proposal is an ongoing or continuation project.

g. If the services of a consultant are required, principal investigators should consider current applicable VA rules and regulations before developing their budgets. Any consultant paid $500 or more per consultation, exclusive of expenses, or $2,500 or more per year must be approved by the Secretary of Veterans Affairs (a time-consuming procedure).

(1) For each consultant listed, provide a justification on VA Form 10-1313-4, Estimated Expenses for Each Year, that indicates the nature of the service to be performed, the fee for each consultation, the amount of travel and per diem, and the number of consultations.

(2) Expenses related to the consultation, not including payment for services (i.e., travel expenses), are to be listed under "ALL OTHER EXPENSES." Travel expenses for non-government personnel are to be identified separately from travel for government employees.

(3) Include with the letters of endorsement at the end of the proposal a letter from each person agreeing to consult and detailing the nature of the consultation. A curriculum vitae for each proposed consultant needs to be included.

h. List each item of equipment to be purchased and provide justification on VA Form 10-1313-4, for any item for which a need may not be apparent to reviewers or which costs more than $3,000. For major equipment items, indicate how many similar instruments are located at the facility or in nearby laboratories/research areas. Do not submit manufacturer's brochures or photocopies as part of the application. All charges for equipment maintenance must be justified.

i. List supplies by major types such as office supplies, animal supplies, etc.

j. List all other expenses by major category, including rental and contractual fees.

(1) IPAs should be listed here if requested.

(2) Travel costs, including local travel, are permitted for project staff if the travel is related directly to the conduct of the research. List and justify any such travel explicitly on VA Form 10-1313-4. The travel estimate for government employees needs to be listed separately from any travel needs of non-VA personnel or consultants.

(3) Travel costs and registration fees for scientific meetings should not be included.

(4) Expenses for books, journals and professional organization dues are not permitted. Chargeback costs, as well as costs for manuscript preparation, photocopying, printing, publication, and illustrations are not allowed.

(5) Include the total acquisition charges for animal subjects (type, number, per diem) and total charges for Animal Research Facility maintenance of all animal subjects as itemized on the "ANIMAL COMPONENT OF RESEARCH PROTOCOL" statement.

9. VA FORM 10-1313-4

a. Check the appropriate box to indicate this form applies to a project.

b. The total operating expenses for the first year should be identical to the total indicated on VA Form 10-1313-3. Current Funds and First Year Request, for this project. All differences in the operating expenses between years should be fully justified in the space provided.

c. Provide detailed justification for all budget items listed on VA Form 10-1313-3. Use continuation sheets if necessary.

(1) Detailed descriptions of staff roles are not needed here, but need to be included in the project management plan in the text of the proposal. However, it is necessary to indicate total Full-time Equivalent (FTE) requested each year. Indicate whether personal service estimates include fringe benefits, etc.

(2) Travel estimates need to be broken out by year, with a clear distinction between travel to be made by VA and other government employees and travel by non-VA consultants, etc. Government employee travel estimates should be based on contract airfares and Conus per diem rates.

(3) Where appropriate, provide a breakdown of the project budget by phases and year.

10. VA FORM 10-1313-5, Biographic Sketch. Complete for each investigator and collaborator on the project. Begin with the PI, and any co-PIs, followed by co-investigators and other key professional staff (i.e., include all persons who will participate in the design, performance, and professional direction of the proposed research, excluding consultants). Do not include curriculum vitae, either in addition to or in place of VA Form 10-1313-5.

11. VA FORM 10-1313-6, Investigator Bibliography. Complete this form for each investigator and collaborator (everyone with a VA Form 10-1313-5). Do not exceed two pages for each investigator and include a chronological list of all the most important and pertinent publications. Abstracts should be separated from the publications. Do not include publications in preparation or presentations. Use the bibliographic format that has been used for the RDIS. Identify those publications that are a result of the most recent period of VA research support and list them after the collaboration section of the narrative. Literature citations must include the full title of the paper being referenced. If there are no entries on VA Form 10-1313-6, "NONE" should be entered. Do not include curriculum vitae in addition to or in place of VA Forms 10-1313-5 and 10-1313-6.

12. VA FORM 10-1313-7, Total VA and Non VA Research Support and VA Form 10-1313-8, Total VA and Non-VA Research/Development

a. Complete these forms for each investigator and collaborator on the project (each person with a VA Form 10-1313-5 and 10-1313-6 who is listed on VA Form 10-1313-3) with an effort of 10 percent and greater.

b. Every item listed on VA Form 10-1313-7 must be fully discussed on VA Form 10-1313-8. Simple statements such as "there are no budgetary, scientific or administrative overlaps" are not acceptable.

c. Pending requests must be included even if there is no current support. Identify the Service and complete RR&D assigned project number, if applicable.

13. NON-VA APPLICATIONS: The abstract of the research plan and budget pages for all funded or pending non-VA applications are to be placed after VA Form 10-1313-8.

14. RESUBMISSION: A resubmitted proposal must include a letter (addressed to the Director, RR&D Service) of not more than three pages that addresses each concern of the Board Summary Statement. State in detail what changes were made and how it compares to the previous proposal. This letter should precede the narrative. The new text or changes from the previous proposal should be reflected in the resubmission in italics. Also include six stapled copies of the latest related reviewed proposal and reviewers' reports (critiques). Include fifteen white related copies of the Board Summary Statement.

15. NARRATIVE DESCRIPTION: The importance of a well-written, detailed, concise narrative description (not to exceed eighteen pages) cannot be overemphasized. The proposal must be complete for purposes of rigorous peer review without referral to previous proposal submissions, reviews, or extensive appendices, except when such appendices are deemed necessary to present progress of funded research for a continuation proposal.

a. **Rationale and/or Objectives of the Research**

(1) **Problem Statement.** Briefly define the problem or recognized need that the proposal is designed to address and include the scope and magnitude of the problem. Explain in the

description the rationale for the study and the basis for such determination with citation of supportive and appropriate sources. Also cite other efforts undertaken in the respective research area and why this particular effort is different and needed.

(2) **Hypotheses or Key Questions.** State the hypothesis or hypotheses to be tested or question(s) to be answered by the project.

(3) **Specific Objectives of the Project with a Projected Timetable.** A timetable should be provided to indicate expected progress of the study. Be as specific as possible. List the short and long-term objectives of this research. For long-term objectives, identify expected intermediate milestones. Identify an anticipated timetable for achievement of the short-term objectives. This timetable needs to represent a best estimate. It is recognized that early results may lead investigators to alter their specific objectives and timetable. Such alterations may be completely appropriate, but must be formally described and justified in a letter to the appropriate RR&D Program Analyst requesting approval.

(4) **Current Status.** Describe the current status of work that has been done toward solution of the problem(s) and how this work relates to the hypotheses or questions presented above. This description should be sufficiently complete to demonstrate that the principal investigator is aware of all related research. Research supportive of and contrary to the hypotheses should be quoted and discussed. Care should be taken to keep this discussion concise and relevant to the problem(s), hypotheses, or questions.

(5) **Significance of Research**. Explain the potential research significance of the proposed study, both in general and with particular reference to the specific goals and priorities of VA. Identify any unique ideas or potential contributions that may result from this study. State the specific desired outcomes of the proposed study, i.e., how the particular method, concept or device may be transferred to the VA health care delivery system. Identify opportunities that VA may have to improve disabled veterans' quality of life and to contribute to the field of rehabilitation research and development.

(6) **Relevance of the Proposed work to the VA Patient Care Mission.** In a separate paragraph, briefly indicate the relevance of the proposed work to the VA Patient Care Mission and to problems of VA research.

b. **Background And Work Accomplished**

(1) **Completed Pilot Or Continuation Projects.** For completed pilot or continuation projects (give title and entire project number; per Item #3 of VA Form 10-1313-1), include a report of the progress made since the study's inception. The report should contain detailed information relative to the administrative and scientific completion of the project, whether or not the study met its stated goals, and summarize how funds were appropriately and efficiently used. For continuation projects, state reasons why additional funds are being requested and provide projected project completion date.

(2) **Accomplishments.** Describe accomplishments to date. State any work you and your co-workers have done that is pertinent to this proposal. Provide reasons why this research is

needed. State how it differs from or adds to work previously completed in this field. Charts, graphs, tables, figures or other material should be included that succinctly present significant data. These are not included in the eighteen page count for the narrative but should not exceed three pages. References should not exceed four pages for a grand total of no more than twenty-five pages. List all major publications resulting from work done during the period on which you are reporting. Do not include clinical case reports, summaries, or verbatim records of lectures, review articles, or abstracts of papers presented at meetings. Submit six copies of each pertinent paper (no more than three) to support progress.

c. **Work Proposed**

(1) **Methodology**. Give details of the research plan including descriptive examples of the type of experiments or other work proposed, the major methods to be used, including the specific techniques, e.g., instrumentation, statistical methods to be employed, the kinds of data to be obtained and the statistical analyses to be used. When animals will be used in the project, list the number and types, including strains and species. Methods need to include the following sections depending on the particular study:

(a) For Human Studies:

1. Experimental Design and Timetable (be as specific as possible).

2. Patient Selection Criteria - Informed Consent.

3. Intervention and Training Methods.

4. Outcomes to be Measured.

5. Data Collection Methods.

6. Analysis.

(b) For Animal Studies:

1. Experimental Design and Timetable (be as specific as possible).

2. Intervention.

3. Measurements (detailed methods to meet each objective).

4. Data Collection Methods.

5. Analysis.

(2) **Resources.** Describe the facilities and personnel required for the project. Indicate which are available and which must be obtained, including office and laboratory space, data processing

facilities, clinical research wards, access to specific patients, access to VA staff, animal rooms, and major equipment and/or supply items.

(3) **Collaboration.** Describe any proposed collaboration with institutions and investigators. Include a description of the role of additional professional persons.

(4) **Literature References.** Cite key references and list full title, authors and dates of publications. Include complete titles of articles as well as books and journals.

16. LETTERS OF ENDORSEMENT. Formal letters from the following must be attached to an RR&D proposal:

a. The Director of the PI's VA healthcare facility. The letter must contain statements that:

(1) The Director understands the potential impact of the proposed research on the facility's organization;

(2) The Director endorses the proposed project; and

(3) The space and necessary support of the VA facility will be available if the project is approved for funding by RR&D Service.

b. The appropriate official of any collaborating institution. The letter must contain the same information as required in subparagraphs 16a(1), 16a(2) and, if appropriate, 16a(3).

c. A letter indicating the proposal has been reviewed and endorsed by the Chairman of the local VA R&D Committee.

d. An indication of concurrence from each participating or affected organizational element is required.

e. The specific role each individual named as a consultant or collaborator has in the project is to be detailed. A curriculum vitae of each consultant is required.

17. INQUIRIES AND ADDITIONAL INFORMATION: Inquiries may be directed to RR&D Service, Program Analysis and Review Section (PARS), at (202) 408-3670. Refer also to the RR&D web-site at www.vard.org.